

June 19, 1997

**MEDICAID CLINICAL LABORATORY IMPROVEMENT  
AMENDMENTS (CLIA) IMPLEMENTATION**

**RELEASE No. 31**

Dear State Medicaid Director:

**PLEASE CONVEY TO MEDICAID CLAIMS PROCESSORS IMMEDIATELY!**

The purpose of this letter is to advise all Medicaid State Agencies (MSAs) to commence to deny payments to all laboratories submitting claims for services not covered by a CLIA certificate and for all claims for services rendered outside effective dates of a CLIA certificate beginning with claims processed on or after January 1, 1998. MSAs will have a window of 6 months starting with January 1 to initiate the action to deny these payments. States are given this flexibility to enforce these requirements within the designated time period since there are so many variables in State operations which must be modified to meet this new requirement.

Prior to this notification MSAs denied payments only to non-physician laboratories. Now all labs will be affected by CLIA claims processing editing. This will include editing all claims for:

- labs which do not have a CLIA certificate,
- labs submitting claims for services not covered by CLIA certificate, and
- labs submitting claims for services rendered outside the effective dates of the CLIA certificate.

Effective October 1, MSAs will decide, individually, if or where the CLIA number shall be placed on the billing form for claims submitted for Medicaid payment. Some States already have procedures in place that will not require the CLIA number to be on the billing form. Those MSAs that need the CLIA number on the form should use the time between October and January to update their records. There is already space for the CLIA number for those physician-owned labs (POLs) that submit their claims electronically.

HCFA has met with the American Medical Association (AMA), the American Society of Internal Medicine (ASIM), and the American Academy of Family Physicians (AAFP) to inform them of this decision. MSAs must launch an intensive educational program to inform labs, specifically POLs, that submitted claims will be denied if they do not meet CLIA requirements for claims submitted starting January 1 or when the State staff modify their software to edit this type of claim. MSAs should use methods to broadcast this information that have worked for them in the past.

Medicare carriers will:

- deny payments to the top offending shared labs that do not certify under CLIA starting July 1, 1997,
- send alerts to shared labs not complying with CLIA requirements starting October 1, 1997, and
- deny all claims not meeting CLIA requirements starting January 1, 1998.

Effective October 1, 1997 HCFA will require the POLs' CLIA number on the HCFA-1500 billing form in item 23 as a condition for Medicare payment. POLs without a CLIA number on the 1500 billing form will receive a notice from the carrier that these services will be denied starting January 1, 1998. POLs will have a grace period from October 1, 1997 to January 1, 1998 to begin using the correct CLIA number, to renew an application, or to apply and receive a CLIA certificate and number. The grace period will allow carriers and POLs an opportunity for communication and education.

This will require Medicare to contact most of the labs faced with the possibility of denied claims and to resolve the CLIA certification issue before MSAs begin to deny claims in January or later. MSAs should contact affected labs anyway to ensure that the information gets to all labs.

In CLIA Release number 30 we attached a copy of the "proposed" CLIA MSA layout. With this release we have attached a copy of the "final" CLIA MSA layout. We have increased the two-character year to four characters so that we can readily differentiate the 1900 and 2000 years. We have also added the National Provider Identifier (NPI) number. The description for the certificate type (record type 3) has been changed to be consistent with the Online Survey Certification and Reporting (OSCAR) system and Medicare. We have, with this layout, added a new record type to be used in the future to capture ownership information. This new record type (record type 8) is the Ownership Information Record. Although no information exists in the system for this new record yet, we are providing the layout to States so that programming efforts can be accomplished now and when the data are available States will automatically be prepared to receive it. MSA's will be informed when these data are available at a later date. The changes effect the size of the record and block.

All State users must have the new layout/codes ready to take effect by January 1, 1998. As usual, when HCFA makes massive changes to the data we arrange to send all MSAs a cartridge/tape containing the entire file. This procedure is more desirable than the excessive time required to download the entire file. For those MSAs using the Report 91 to download their data at least weekly and do not wish to have a full cartridge/tape sent to them we will make available a file containing only the CLIA ID number and the associated NPI number. Caution must be used by States using the CLIA number/NPI number file to ensure that programming of the new layout also converts the certificate type.

Prior to the implementation date we will coordinate sending the cartridge/tape or file to coincide with the change to the programs (Report 91) used to download updated CLIA data. We request that you order the file prior to November 28. If we do not receive a request for the CLIA ID/NPI number file prior to November 28, we will automatically send the cartridge/tape containing all data.

Refer comments, questions, and requests to Medford J. Campbell, Jr. at (410) 786-4457 or Mary Linda Morgan at (410) 786-2011.

/s/ David Cade

Judith D. Moore  
Acting Director  
Medicaid Bureau

Attachment

cc:

All Regional Administrators

All Associate Regional Administrators - Division of Medicaid

Lee Partridge - American Public Welfare Association

Joy Wilson - National Conference of State Legislatures

Jennifer Baxendell - National Governors' Association

Lloyd Bishop - Office of Legislative & Inter-Governmental Affairs, HCFA

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## **Data File for Medicaid State Agencies (MSAs)**

### **CLIA Implementation**

### **Final Layout for January 1998 Implementation**

### **RECORD LAYOUTS**

- MSA Header Record

Field	Length	From	To	Alpha/ Numeric	Description
Record type	1	1	1	N	0 (zero)
Title	18	2	19	A	CLIA HEADER - MSA
File creation date	8	20	27	N	YYYYMMDD
Filler	133	28	160		

- MSA Laboratory Record

Field	Length	From	To	Alpha/ Numeric	Description
Record type	1	1	1	N	1 (one)
CLIA ID number	10	2	11	A/N	CLIA number

NPI number	10	12	21	A/N	National Provider Identifier
Payment indicator	1	22	22	A	Y = Paid
EIN/SSN	9	23	31	N	Employer ID # (Part B)
Provider number	6	32	37	A/N	Part A Institutional Provider #
Name	25	38	62	A/N	Laboratory name
Street	30	63	92	A/N	Street address
City	28	93	120	A/N	City name
State	2	121	122	A	State abbreviation
Zip	9	123	131	A/N	Zip code
Update code	1	132	132	A	D = Delete A = Add

					U = Update/Change
Update date	8	133	140	N	YYYYMMDD
Filler	20	141	160		

June 13, 1997 - Final layout for January 1, 1998 implementation

- MSA Certificate Record (occurs 1 to 10 times depending upon number of certificates issued)

Field	Length	From	To	Alpha/ Numeric	Description
Record type	1	1	1	N	3 (three)
CLIA ID number	10	2	11	A/N	CLIA number
Certificate type	1	12	12	N	1 = Regular 2 = Waiver 3 = Accreditation 4 = Provider-performed Microscopy Procedure (PPMP) 5 = Partial Accredited

					9 = Registration
Type of laboratory	1	13	13	N	1 = Independent 2 = Physician-owned
Certificate number	2	14	15	N	Latest certificate issued is always = 1
Effective date	8	16	23	N	YYYYMMDD
Expiration date	8	24	31	N	YYYYMMDD
Update code	1	32	32	A	D = Delete A = Add U = Update/Change
Update date	8	33	40	N	YYYYMMDD
Filler	120	41	160		

June 13, 1997 - Final layout for January 1, 1998 implementation

- MSA Specialty/Subspecialty Record (multiple type record)

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Field	Length	From	To	Alpha/ Numeric	Description
Record type	1	1	1	N	5 (five)
CLIA ID number	10	2	11	A/N	CLIA number
LC	3	12	14	N	Laboratory Code
Effective date	8	15	22	N	YYYYMMDD
Expiration date	8	23	30	N	YYYYMMDD
LC	3	31	33	N	Laboratory Code
Effective date	8	34	41	N	YYYYMMDD
Expiration date	8	42	49	N	YYYYMMDD
LC	3	50	52	N	Laboratory Code
Effective date	8	53	60	N	YYYYMMDD



Expiration date	8	61	68	N	YYYYMMDD
LC	3	69	71	N	Laboratory Code
Effective date	8	72	79	N	YYYYMMDD
Expiration date	8	80	87	N	YYYYMMDD
LC	3	88	90	N	Laboratory Code
Effective date	8	91	98	N	YYYYMMDD
Expiration date	8	99	106	N	YYYYMMDD
LC	3	107	109	N	Laboratory Code
Effective date	8	110	117	N	YYYYMMDD
Expiration date	8	118	125	N	YYYYMMDD
LC	3	126	128	N	Laboratory Code

Effective date	8	129	136	N	YYYYMMDD
Expiration date	8	137	144	N	YYYYMMDD
Filler	16	145	160		

June 13, 1997 - Final layout for January 1, 1998 implementation

\* NOTE: Laboratory codes are stored in ascending order then in descending order by effective date for each laboratory code.

- MSA Proficiency Testing (HCPCS) Record (multiple type record)

Field	Length	From	To	Alpha/ Numeric	Description
Record type	1	1	1	N	7 (seven)
CLIA ID number	10	2	11	A/N	CLIA number
PT code	5	12	16	N	HCPCS

Effective date	8	17	24	N	YYYYMMDD
Expiration date	8	25	32	N	YYYYMMDD
PT code	5	33	37	N	HCPCS
Effective date	8	38	45	N	YYYYMMDD
Expiration date	8	46	53	N	YYYYMMDD
PT code	5	54	58	N	HCPCS
Effective date	8	59	66	N	YYYYMMDD
Expiration date	8	67	74	N	YYYYMMDD
PT code	5	75	79	N	HCPCS
Effective date	8	80	87	N	YYYYMMDD
Expiration date	8	88	95	N	YYYYMMDD

PT code	5	96	100	N	HCPCS
Effective date	8	101	108	N	YYYYMMDD
Expiration date	8	109	116	N	YYYYMMDD
PT code	5	117	121	N	HCPCS
Effective date	8	122	129	N	YYYYMMDD
Expiration date	8	130	137	N	YYYYMMDD
PT code	5	138	142	N	HCPCS
Effective date	8	143	150	N	YYYYMMDD
Expiration date	8	151	158	N	YYYYMMDD
Filler	2	159	160		

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- Ownership Information Record (multiple type record)

Field	Length	From	To	Alpha/ Numeric	Description
Record type	1	1	1	N	8 (eight)
CLIA ID number	10	2	11	A/N	CLIA number
First name	40	12	51	A/N	
Middle name	20	52	71	A/N	
Last name	40	72	111	A/N	
Suffix name	3	112	114	A/N	
Date of birth	8	115	122	N	YYYYMMDD
Social Security Number	9	123	131	N	
Employer ID Number	9	132	140	N	Employer ID # (Part B)

Percent of ownership	3	141	143	N	Whole percentage
Ownership starting date	8	144	151	N	YYYYMMDD
Ownership ending date	8	152	159	N	YYYYMMDD
Filler	1	160	160		

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- MSA Trailer Record

Field	Length	From	To	Alpha/ Numeric	Description
Record type	1	1	1	N	9 (nine)
Title	19	2	20	A	CLIA TRAILER - MSA
Delete Transactions	8	21	28	N	Record count (Update code = D)

Update Transactions	8	29	36	N	Record count (Update code = U)
Add Transactions	8	37	44	N	Record count (Update code = A)
Total Transactions	9	45	53	N	Total number of records in this transmission
Laboratory records	8	54	61	N	Record count (Record type = 1)
Certificate records	8	62	69	N	Record count (Record type = 3)
Specialty records	8	70	77	N	Record count (Record type = 5)
PT (HCPCS) records	8	78	85	N	Record count (Record type = 7)
Ownership records	8	86	93	N	Record count (Record type = 8)
Filler	67	94	160		

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Tape/Cartridge Characteristics

3480 Cartridge

IBM standard label  
Record length - 160  
Block size - 28800  
Fixed block

IBM Tape

6250 BPI  
9 Track  
IBM Standard label  
Record length - 160  
Block size - 14400  
Fixed block

\* NOTE: A cartridge will be sent unless we are notified to send IBM tape.